A. Provisions of the Proposed Rule affecting Standards, Implementation Specifications, Certification Criteria, and Definitions

§ 170.315(a)(1) Computerized provider order entry – medications	
Included in 2015 Edition Base EHR Definition? Yes, as an alternative to § 170.315(a)(2) or (3)	
Stage 3 MU Objective : Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.	
2015 Edition Health IT Certification Criterion (1) Computerized provider order entry – medications. Technology must enable a user to record, change, and access medication orders.	
Preamble FR Citation: 80 FR 16814	**Specific questions in preamble?** *Yes*

Public Comment Field:

We agree with proposal for three separate certification criteria for order entry of medications, labs and imaging studies. Doing so allows for greater opportunity for product innovation, as well as increased standardization through the use of controlled vocabularies unique to each particular order type.

Vendors seeking certification for order entry modules should be required to prove that EHR can restrict which end-user can place orders based upon configuration settings and user role in organization; conversely, testing should demonstrate that order entry fails if user does not have appropriate qualifications/credentials.

§ 170.315(a)(21) Social, psychological, and behavioral data

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(2) Social, psychological, and behavioral data. Enable a user to record, change, and access, at a minimum, one of the following patient social, psychological, and behavioral data.

(i) Sexual orientation. Enable sexual orientation to be recorded in accordance with the standard specified in § 170.207(o)(1) and whether a patient declines to specify sexual orientation.

(ii) Gender identity. Enable gender identity to be recorded in accordance with the standard specified in § 170.207(o)(2) and whether a patient declines to specify gender identity.

(iii) Financial resource strain. Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(o)(3) and whether a patient declines to specify financial resource strain.

(iv) Education. Enable education to be recorded in accordance with the standard specified in § 170.207(o)(4) and whether a patient declines to specify education.

(v) Stress. Enable stress to be recorded in accordance with the standard specified in § 170.207(o)(5) and whether a patient declines to specify stress.

(vi) Depression. Enable depression to be recorded in accordance with the standard specified in § 170.207(o)(6) and whether a patient declines to specify stress.

(vii) Physical activity. Enable physical activity to be recorded in accordance with the standard specified in § 170.207(o)(7) and whether a patient declines to specify physical activity.

(viii) Alcohol use. Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(o)(8) and whether a patient declines to specify alcohol use.

(ix) Social connection and isolation. Enable social connection and isolation to be recorded in accordance the standard specified in § 170.207(o)(9) and whether a patient declines to specify social connection and isolation.

(x) Exposure to violence (intimate partner violence). Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in § 170.207(o)(10) and whether a patient declines to specify exposure to violence (intimate partner violence).

Preamble FR Citation: 80 FR 16826

Specific questions in preamble? *Yes, and also see requests for comment on work information (industry/occupation) data and U.S.uniformed/military service data*

Public Comment Field:

Overall we agree with the proposal to broaden certification to include social, psychological and behavioral data – all of which can have significant impact on healthcare delivery and outcomes. However, we disagree with recommendation(s) to adopt certification criteria that currently lack associated standardized codes. In this particular section this would apply to the following: Financial resource strain (iii), Stress (v), Social connection and Isolation (ix), and Exposure to violence (x). If LOINC codes are ultimately created and approved for these topics they can be added as certification criteria during a later rulemaking process.

ONC should use extreme caution when creating certification criteria based upon standards that are pending, non-existent, or unproven. Reliance upon standards is not fully vetted or proven and only adds to the confusion, as well as increase the risk of systemic failure.

§ 170.315(b)(1) Transitions of care

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.

2015 Edition Health IT Certification Criterion

(1) Transitions of care.

(i) Send and receive via edge protocol. Technology must be able to:

(A) Send transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d); and

(B) Receive transitions of care/referral summaries through a method that conforms to the standard specified at §170.202(d) from a service that has implemented the standard specified in §170.202(a).

(C) XDM processing. Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in § 170.205(p)(1) if the technology is also being certified using an SMTP-based edge protocol.

(ii) Validate and display.

(A) Validate C-CDA conformance – system performance. Technology must demonstrate its ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with both of the standards specified in § 170.205(a)(3) and (4) This includes the ability to:

(1) Parse each of the document types formatted according to the following document templates: CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; Referral Note, and Discharge Summary.

(2) Detect errors in corresponding “document-templates,” “section-templates,” and “entry-templates,” including invalid vocabulary standards and codes not specified in either of the standards adopted in § 170.205(a)(3) and (4);

(3) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from either of the standards adopted in § 170.205(a)(3) and (4);

(4) Correctly interpret empty sections and null combinations; and

(5) Record errors encountered and allow for a user to be notified of or review the errors produced.

(B) Technology must be able to display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in § 170.205(a)(3) and (4).

(C) Section views. Allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with either of the standards adopted in § 170.205(a)(3) and (4).

§ 170.315(b)(1) Transitions of care

2015 Edition Health IT Certification Criterion (b)(1) Transitions of care, continued

(iii) Create.

(A) Enable a user to create a transition of care/referral summary:

(1) Formatted according to the standards adopted in § 170.205(a)(3);

(2) Formatted according to the standards adopted in § 170.205(a)(4); and

(3) Includes, at a minimum, the Common Clinical Data Set and the following data expressed, where applicable, according to the specified standard(s):

(i) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified §170.207(a)(4);

(ii) Cognitive status;

(iii) Functional status;

(iv) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information; and

(v) Inpatient setting only. Discharge instructions.

(B) Patient matching data quality. Technology must be capable of creating a transition of care/referral summary that includes the following data and, where applicable, represent such data according to the additional constraints specified below:

(1) Data. first name, last name, maiden name, middle name (including middle initial), suffix, date of birth, place of birth, current address, historical address, phone number, and sex.

(2) Constraint. Represent last/family name according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0.

(3) Constraint. Represent suffix according to the CAQH Phase II Core 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule version 2.1.0 (JR, SR, I, II, III, IV, V, RN, MD, PHD, ESQ). If no suffix exists, the field should be entered as null.

(4) Constraint. Represent the year, month and date of birth are required fields while hour, minute and second should be optional fields. If hour, minute and second are provided then either time zone offset should be included unless place of birth (city, region, country) is provided; in latter local time is assumed. If date of birth is unknown, the field should be marked as null.

(5) Constraint. Represent phone number (home, business, cell) in the ITU format specified in ITU-T E.123 and ITU-T E.164. If multiple phone numbers are present, all should be included.

(6) Constraint. Represent sex in accordance with the standard adopted at § 170.207(n)(1).

Preamble FR Citation: 80 FR 16831 **Specific questions in preamble?** *Yes*

Public Comment Field:

In other sections of our response for comments we have stressed the support for adopting the most recent, applicable and fully-balloted HL7 standard. For this specific criterion we express the same level of support for sole adoption of the standard proposed at § 170.205(a)(4) (C-CDA version R2.0); we do not endorse continued use of C-CDA version R1.1.

The attempt to minimize risk of bilateral asynchronous cutover under existing proposal is done at the expense of increased complexity and redundancy. Systems would have to generate and parse two separate documents that ostensibly contain the same data. This would establish a precedence that is likely untenable in the long run – the constant need to operationalize and accommodate for backwards compatibility. HL7 C-CDA Implementation Guides are technically challenging to hospital IT staff tasked with configuring their EHR systems; requiring knowledge of both versions is overly burdensome. The knowledge gap and general lack of understanding of HL7 standards contribute to this problem. Vendors also find it challenging to implement the HL7 standard in a way that ensures interoperability during transitions of care.

Lastly, anyone who has attempted to validate any HL7 document using existing schema and schematron files will encounter a vicious cycle, whereby correcting errors generated by one validation file leads to the creation of a different set of errors from the other validation file; this is made worse if tester inadvertently uses an older version of either validation file. Use of two separate versions of the same standard (R1.1 and 2.0) would multiply this negative effect and make the validation process exponentially more complicated.

§ 170.315(c)(1) Clinical quality measures – record and export

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(1) Clinical quality measures – record and export.

(i) Record. For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason."

(ii) Export. A user must be able to export a data file formatted in accordance with the standard specified at § 170.205(h) for one or multiple patients that includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

Preamble FR Citation: 80 FR 16842 **Specific questions in preamble?** *Yes*

Public Comment Field:

Three separate proposals were made regarding which standard should be adopted for certification of this criterion. Of the three, we support and recommend use of Option #2 (**HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture (QRDA), DSTU Release 2 (July 2012) and the September 2014 Errata**) as this is the most up to date and comprehensive eCQM reporting standard. Significant development work by vendors, developers, and clinical IT staff has been done using this standard and in spite of known issues, it remains the best existing standard. As ST3 will not be fully implemented until 2018, relying on a 2012 version of this standard does not seem prudent.

We agree and support the recommendation that end users be able to generate CQM reports *ad hoc* without direct vendor assistance. Currently, many of the providers we work with are unable to access and create these reports. Most have never received any guidance from their vendor on the topic; a significant number are unaware of their existence within the EHR and cannot create any reports without third-party vendor assistance – a costly and time consuming practice. Additionally, adopting this certification criterion allows for a quicker, real-time feedback loop for the provider in order to better resolve quality of care issues.

We strongly disagree with ONC's option to adopt a "QRDA-like" standard based upon an "anticipated" release of a standard (QUICK FHIR-based DSTU.CQM) that is not even available for review during the comment period.

§ 170.315(c)(2) Clinical quality measures – import and calculate

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(2) Clinical quality measures – import and calculate.

(i) Import. Enable a user to import a data file in accordance with the standard specified at § 170.205(h) for one or multiple patients and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

(ii) Technology must be able to calculate each and every clinical quality measure for which it is presented for certification.

Preamble FR Citation: 80 FR 16843 **Specific questions in preamble?** *Yes*

Public Comment Field:

We support the proposal to remove the exemption that currently allows vendors to exclude the data import functionality when seeking certification for any of the eCQM certification criteria. This loophole has been exploited by vendors and created confusion among providers on what capabilities their EHR actually do possess in LIVE or PRODUCTION environment.

In response to ONC's specific question regarding sample size for testing and certification we suggest a minimum of one hundred (100) and maximum of five hundred (500). Sample sizes larger than 500 would place an unnecessary testing burden on vendors who predominantly create IT products for smaller hospitals – i.e. organizations that typically have a very low patient population.

Reserved for § 170.315(c)(3) Clinical quality measures – report

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(3) [Reserved]

Preamble FR Citation: 80 FR 16844 **Specific questions in preamble?** *No*

Public Comment Field:

No proposed criteria, only an announced "intent" to propose in conjunction with annual PQRS and/or IQR program changes. While recognizing the need to align multiple programs, this would in effect create the need for annual certification of an EHR's capability to report, as CMS has already announced their intent to modify the reporting requirements for PQRS & IQR annually. For the 2015 IQR program most of the additional constraints/requirements offer little in the way of useful information but create a substantial obstacle to the QRDA file validation process, as the schematron with CMS constraints is not publicly available.

§ 170.315(c)(4) Clinical quality measures – filter

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(4) Clinical quality measures – filter.
- (i) Technology must be able to record the data listed in paragraph (c)(4)(iii) of this section in accordance with the identified standards, where specified.
- (ii) Technology must be able to filter CQM results at the patient and aggregate levels by each one and any combination of the data listed in paragraph (c)(4)(iii) of this section.
- (iii) Data.
  - (A) TIN;
  - (B) NPI;
  - (C) Provider type;
  - (D) Patient insurance;
  - (E) Patient age;
  - (F) Patient sex in accordance with, at a minimum, the version of the standard specified in § 170.207(n)(1);
  - (G) Patient race and ethnicity in accordance with, at a minimum, the version of the standard specified in § 170.207(f)(2);
  - (H) Patient problem list data in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4); and
  - (I) Practice site address.

Preamble FR Citation: 80 FR 16844 **Specific questions in preamble?** *Yes*

We support adoption of this criterion with a directed response to ONC's request for comment on the use of other payer value sets. The National Library of Medicine's Value Set Authority already contains an extensive list of payer codes (~150). As these value sets are the default standard for QRDA reports, we do not see any need to expand or use alternative value sets.

§ 170.315(f)(1) Transmission to immunization registries

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

The EP, eligible hospital, or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

2015 Edition Health IT Certification Criterion

(1) Transmission to immunization registries.
- (i) Technology must be able to create immunization information for electronic transmission in accordance with:
  - (A) The standard and applicable implementation specifications specified in § 170.205(e)(4);
  - (B) At a minimum, the version of the standard specified in § 170.207(e)(3) for historical vaccines; and
  - (C) At a minimum, the version of the standard specified in § 170.207(e)(4) for administered vaccines.
- (ii) Technology must enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4).

Preamble FR Citation: 80 FR 16850 **Specific questions in preamble?** *Yes*

§ 170.315(f)(1) Transmission to immunization registries

Public Comment Field:

Overall the proposal seems reasonable and we do feel that there are some benefits as described in the NPRM.
The change in code set broadly impacts what EHR vendors and immunization information systems currently support today.

§ 170.315(g)(6) Consolidated CDA creation performance

Included in 2015 Edition Base EHR Definition?

No, but a conditional certification requirement

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(1) Consolidated CDA creation performance. The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iii) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially.

- (i) Reference C-CDA match. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that matches a gold-standard, reference data file.
- (ii) Document-template conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates a valid implementation of each of the following document templates (as applicable to the adopted standard):
  - (A) Generally applicable. CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.
  - (B) Inpatient setting only. Discharge Summary.
- (iii) Vocabulary conformance. Upon the entry of clinical data consistent with the Common Clinical Data Set, the technology must be able to create a data file formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that demonstrates the required vocabulary standards (and value sets) are properly implemented.

Preamble FR Citation: 80 FR 16859 **Specific questions in preamble**? *Yes*

Public Comment Field:

Refer to § 170.315(b)(1) for comments on C-CDA in support of 170.205(a)(4) as sole standard for this & related criteria.